

## Budget Year Four Workplan

For each Recipient Activity applicants should complete the work plan templates attached below. Applicants are welcome to use bullet-point format in their answers, so long as the information is clearly conveyed in the response. All responses should be brief and concise. **Please note that full use of the CDC templates will meet all of the requirements for submission of a progress report and work plan.** Although no additional information is required, grantees may elect to submit other essential supporting documents via the web portal by uploading them as additional electronic files.

**CRITICAL CAPACITY #10 (Level-One Laboratories):** To develop and implement a jurisdiction-wide program that provides rapid and effective laboratory response for chemical terrorism by establishing competency in collection and transport of clinical specimens to laboratories capable of measuring chemical threat agents.

### RECIPIENT ACTIVITIES:

1. **CRITICAL BENCHMARK #15 – APPLICABLE TO LEVEL-ONE LABORATORIES:** Hire and train a chemical terrorism laboratory coordinator (chemist or medical technologist) and assistant coordinator to advise the laboratory director, the State Terrorism Coordinator and other public health and environmental health officials about chemical terrorism incidents and preparedness. These individuals are responsible for ensuring the proper collection, labeling, and shipment of blood, urine, and other clinical specimens required in response to known or suspected chemical terrorism incidents and for ensuring associated data and communication requirements are met.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

Massachusetts State Laboratory Institute will assemble a professional chemical terrorism team to advise the laboratory director, the State Emergency Preparedness Coordinator and other public and environmental health officials regarding chemical terrorism agents, incidents and related emergency response. A chemical terrorism coordinator and an assistant coordinator will be hired to integrate emergency preparedness for chemical incidents into the MDPH emergency response plan, *Massachusetts Emergency Support Function (MAESF) 8* and the laboratory emergency response plan. A key component of the revised laboratory plan will be to ensure that biological specimens taken from exposed or potentially exposed individuals are collected, identified and transported in accordance with the instructions posted on the Laboratory Response Network (LRN). MSLI has a detailed protocol for packing and shipping of diagnostic specimens and infectious agents, which is in accordance with International Air Transport Association (IATA) 650 and US Department of Transportation regulations. It is available on-line in Section 6 of the *MSLI Manual of Testing Services* at <http://www.state.ma.us/dph/sli>.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Develop job descriptions, advertise positions, conduct interviews, conduct background

investigations.

- Develop relationships with state, federal and local public and environmental health officials involved in emergency preparedness for a chemical terrorism incident.
- Develop relationships with HazMat, Civil Support Teams and other first responders.
- Establish a chemical terrorism work group in the *Bioterrorism Emergency Preparedness and Response Program Advisory Committee*.
- Attend *Advisory Committee* meetings.
- Expand the scope of the laboratory emergency response plan to include responding to a chemical terrorism or suspected chemical terrorism incident.
- Develop detailed protocols consistent with the LRN guidelines for the collection, labeling and shipping of biological specimens taken from exposed or potentially exposed persons.
- Provide training and educational materials to Massachusetts' hospitals, laboratories and local health agents regarding chemical terrorism and emergency response.
- Attend 50 state Focus Area C/D meeting in the winter of 2004.

*Timeline: What are the critical milestones and completion dates for each task*

- Develop and disseminate specific protocols for the collection, handling and transport of biological specimens from exposed and potentially exposed individuals in accordance with LRN guidelines, DOT and IATA regulations. *Completed September 2000*

#### October 2003

- Initiate hiring process for CT coordinator and assistant. *Expected completion date December 31, 2003. (JN)*
- Enhance relationships with local, state and federal public and environmental health officials. *On-going activity (RT,JN, MG,CT staff)*
- Enhance relationships with first responders. *On-going activity (RT,JN, MG, CT staff)*

#### January 2004

- Establish a CT workgroup. *On-going activity (JN, RT, MG)*
- Integrate CT activities into the Laboratory Emergency Response Plan. Coordinate with Focus Area C activities. *Expected completion date June 30, 2004. (CT Coordinator, MG)*

#### May 2004

- Conduct needs assessment, and develop educational materials relating to CT agents and emergency response for hospitals, commercial laboratories, medical community and local health departments. *Expected completion date September 30, 2004. (CT Coordinator)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

Julianne Nassif, Director, Analytical Chemistry Laboratories

Ralph Timperi, Director, State Laboratory Institute

Chemical Terrorism Staff - to be hired

Mariah Grazioplene, Laboratory Emergency Preparedness Coordinator

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Project objectives, tasks, milestones and deadlines will be carefully tracked using Microsoft Project software. Chemical terrorism staff will join existing weekly bioterrorism meetings, chaired by Assistant Commissioner Timperi, where laboratory and emergency planning activities progress are evaluated, information is shared and problems are discussed and will join emergency response and preparedness program managers weekly meetings.

2. Develop a component, incorporated within the comprehensive response plan that directs how public health, food testing, environmental testing, and other laboratories within your jurisdiction will respond to a chemical terrorism incident. The plan must include (a) roles and responsibilities, (b) inter- and intra-jurisdictional surge capacity, (c) a description of how the plan integrates with other department-wide emergency response efforts, (d) protocols for the safe transport of specimens by air and ground, and (e) a mechanism for reporting laboratory data to public health officials, law enforcement agencies, and other chemical terrorism LRN laboratories. **(LINK WITH ALL OTHER FOCUS AREAS)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

In order to develop and implement a response system that allows for analysis of a variety of sample types including; drinking water, soil, air, surface wipes and foods and beverages, MSLI will work cooperatively with state and federal food and environmental laboratories located in Massachusetts to assess their existing capability and capacity for CT agents. Considerable analytical expertise and equipment is available at both the Massachusetts Department of Environmental Protection Wall Experiment Station and the US Environmental Protection Agency Region 1 Laboratory for the analysis of organic and inorganic chemicals in environmental matrices. There may be some limited capacity for chemical analysis of food products at the Massachusetts Department of Food & Agriculture Pesticide Laboratory and the US Food & Drug Administration Winchester Engineering & Analytical Center. In addition, MSLI has some experience and capacity for measuring chemical agents in environmental media and foods.

The Massachusetts State Laboratory Institute is applying as a Level 2 laboratory for chemical agents in blood, serum and urine, with the goal of pursuing Level 3 capability in the next funding cycle.

*The Laboratory Response Network Policy Regarding Evaluation of Laboratories for Entry*

*into Confirmatory Levels of the Laboratory Response Network*, agreed to by the Association of Public Health Laboratories (APHL) and CDC in November, 2002, states that the State Public Health Laboratory Director (SPHLD) based on an assessment of response capacity within the state, determines a specific need for additional support from non-public health laboratory to meet the counter-terrorism mission of the state, the SPHLD may recommend consideration of a non-public health laboratory to the LRN.

MSLI working in cooperation with other MDPH divisions and the state and federal environmental and food agencies will develop a plan that provides for rapid response to a genuine or suspected chemical terror incident with sufficient functional redundancy and surge capacity. Specifically, the emergency response plan will need to identify individual laboratory capability and capacity and their respective roles and responsibilities; address issues that cross-traditional agency and geographic and political jurisdictions with appropriate Memoranda of Understanding. At this time, we will not be recommending additional, non-SPHL laboratories for inclusion in the LRN but we will evaluate the needs and capabilities and consider others after that thorough assessment.

The laboratory response plan is coordinated through a Department Bioterrorism Workgroup that meets biweekly to assure effective communication between DPPH and federal, state and local agencies through an all-hazards response approach. In addition, DPH has imbedded employees at the Massachusetts Emergency Management Agency (MEMA) and the State Fire Services (Regional HazMat Response Units) to assure coordination with the state emergency response plans. Further, there is a Statewide Advisory Committee with several Workgroups that meet regularly to plan, implement and coordinate all aspects and Focus Areas of the CDC and HRSA emergency preparedness grants. The State Laboratory has representation at each of these Advisory Committee and Workgroup meetings

As part of emergency preparedness activities over the past three years, MSLI has developed detailed protocols for the safe packaging and shipping protocols of diagnostic specimens and infectious agents in accordance with IATA and DOT regulations. This protocol ensures the appropriate, safe containment of diagnostic specimens for ground and air transport, including those specimens from individuals exposed or potentially exposed to chemical terrorism agents.

Identifying hospital, clinical, environmental, food testing and commercial laboratories within Massachusetts who may have some role in a chemical terrorism incident is an important aspect of emergency response and effective communication of laboratory data. MSLI currently maintains a database of hospital laboratories in Massachusetts who have attended Level A microbiological training. This system which stores information regarding laboratory director, their contact information (address, phone, fax, email), and the names of individuals trained is a good foundation for developing a comprehensive database for all laboratories in the state who may have a role in a chemical terrorism incident. To accomplish this, MSLI will survey laboratories within Massachusetts to collect information relating to the laboratories' testing capabilities and practices in addition to the physical location and appropriate contact information. The comprehensive database will be extremely useful for rapidly communicating information and for

tracking purposes.

Currently, laboratory data and emergency notices are blast faxed to hospital laboratories, first responders, local health agents and others as appropriate. Within the next year, these entities will be encouraged to join the *Massachusetts Alert Network*. The MAN a secure web based application interfaced with a variety of devices (e.g. pager, fax, phone, email, wireless), which provides the infrastructure necessary for continuous, secure, bi-directional communication and information sharing in support of aspects of emergency preparedness, including but not limited to response planning, educational services, disease surveillance, laboratory reporting and epidemiological investigation.

Hospital laboratories will play an important patient care role following a chemical or radiological emergency. The chemical terrorism coordinator in cooperation with the State Training Advisor will develop and deliver training to area hospitals relating to the chemical agents, sample handling and transport, maintaining chain of custody and the roles of state and community partners.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Meet with laboratory directors from state and federal environmental and food testing laboratories to assess current capabilities and discuss potential roles and responsibilities
- Form a working group comprised of various stakeholders to draft the chemical terrorism sections of the comprehensive Emergency Response Plan
- Consider non-SPHLs for inclusion in the LRN
- Modify shipping & transport protocols as appropriate for chemical agents
- Contract with a courier service for sample delivery
- Consider MOU with other state and federal environmental & food testing laboratories for screening and surge capacity testing
- Consider MOU with other New England states for surge capacity testing
- Survey hospital and commercial laboratories to collect information relating to the laboratories' physical location, contact information, testing capabilities and practices and maintain these data in a comprehensive database for Massachusetts.
- Develop and deliver training sessions to Massachusetts hospitals
  - *Introduction to Chemical Terrorism Agents*
  - *Sample Handling and Transport*
  - *Maintaining Chain of Custody*
  - *The Roles & Responsibilities of State and Community Partners*

*Timeline: What are the critical milestones and completion dates for each task?*

- Develop and disseminate specific protocols for the collection, handling and transport of

biological specimens from exposed and potentially exposed individuals in accordance with LRN guidelines, DOT and IATA regulations. *Completed September 2000*

#### October 2003

- Meet with laboratory directors from state and federal environmental and food testing laboratories to assess current capabilities and discuss potential roles and responsibilities. *Expected completion date November 2003 (JN, RT, MG)*
- Form a working group comprised of various stakeholders to draft the chemical terrorism sections of the comprehensive Emergency Response Plan *Expected completion date r Expected completion date December 2003 (JN, RT, MG)*

#### January 2004

- Contract with a courier service for sample delivery *Expected completion date March 2004 (CT Coordinator)*
- Survey hospital and commercial laboratories to collect information relating to the laboratories' physical location, contact information, testing capabilities and practices and maintain these data in a comprehensive database for Massachusetts. *Expected completion date April 2004 (CT Coordinator)*

#### February 2004

- Develop and deliver training sessions to Massachusetts hospitals
  - *Introduction to Chemical Terrorism Agents*
  - *Sample Handling and Transport*
  - *Maintaining Chain of Custody*
  - *The Roles & Responsibilities of State and Community Partners*

*Expected completion date September 2004 (CT Coordinator, JN, State Training Advisor)*

#### March 2004

- Consider non-SPHLs for inclusion in the LRN. *Expected completion date July 2004 (RT)*
- Consider MOU with other state and federal environmental & food testing laboratories for screening and surge capacity testing. *Expected completion date September 2004 (RT)*
- Consider MOU with other New England states for surge capacity testing. *Expected completion date September 2004 (RT)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Project objectives, tasks, milestones and deadlines will be carefully tracked using Microsoft Project software. Adjustments to timelines will be made as needed after discussion at weekly emergency preparedness meetings.

3. Establish and document in the comprehensive response plan, relationships with local members of HazMat teams, first responders, local, state, and federal law enforcement, and the Army National Guard (WMD-CST) to coordinate laboratory support for response to chemical terrorism with their response activities.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

Local HazMat teams, first responders, law enforcement and the Army National Guard Weapons of Mass Destruction Civil Support Teams are a critical component of any chemical emergency response effort. Equipped with sensitive screening devices such as ion mobility detectors and portable GC/MS. These first responders will provide valuable information regarding the identity of a chemical agent in the ambient environment. These field data will be useful in guiding appropriate medical treatment for victims, site evacuation and re-entry parameters. All first responders are trained in the Incident Command System and operate within its confines, providing for secure and efficient communication of analytical findings.

MSLI has an excellent working relationship with local first responders, law enforcement, HazMat and the Massachusetts Army National Guard 1<sup>st</sup> Civil Support Team, which has evolved over the past several years relating to bioterrorism preparedness issues. The laboratory will build on existing relationships to develop a coordinated response and laboratory support for chemical terrorism incidents and activities. The specific roles and responsibilities will be detailed in the expanded Emergency Response Plan.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Enhance relationships with HazMat, FBI, Massachusetts State Police, local fire and law enforcement and WMD-CST to coordinate emergency response and laboratory activities.
- Document roles, responsibilities and in the Emergency Response Plan coordinated.
- Evaluate field instruments to better understand their capabilities and limitations

*Timeline: What are the critical milestones and completion dates for each task?*

- Enhance relationships with HazMat, FBI, Massachusetts State Police, local fire and law enforcement and WMD-CST to coordinate emergency response and laboratory activities. *Expected completion date March 2004 (CT Coordinator, RT, JN, MG)*
- Document roles, responsibilities and coordinated laboratory response in the Emergency Response Plan. *Expected completion date March 2004 (CT Coordinator, RT, JN, MG)*
- Evaluate field instruments to better understand their capabilities and limitations. *Expected completion date September 2004. (CT Staff)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Expansion of the laboratory response plan to include response to a chemical terrorism incident which is inclusive of the roles and responsibilities of HazMat, FBI, state and local law enforcement and the WMD-CST will indicate successful completion of this activity.

4. Join the chemical terrorism component of the Laboratory Response Network (LRN) and ensure that capacity exists (within the state, through partnerships with Level-Two and/or Level-Three laboratories in other states, or CDC) for validated testing of chemical agents in clinical specimens.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

Currently, the LRN is a secure and effective means of disseminating information, validated protocols and reagents relating to bioterrorism. MSLI is an active member of the LRN having successfully participated in validation studies for the following biological agents: *Bacillus anthracis*, *Brucella sp.*, *Burkholderia sp.*, *Clostridium botulinum*, *Francisella tularensis*, *Yersinia pestis*, *Vaccinia* and *Varicella zoster virus*.

MSLI will join the chemical terrorism component of the LRN and ensure that capacity exists (within state, through partnerships with Level 2 and Level 3 laboratories in other states or CDC) for validated testing of chemical agents in biological specimens.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Join the chemical component of the LRN as a Level Two Laboratory
- Develop detailed protocols for collection, shipping and handling of biological specimens from exposed or potentially exposed individuals.
- Attend training at CDC for analytical methods for trace metals, cyanide and lewisites.
- Implement LRN validated methods for these chemical agents in biological samples at the MSLI.
- Cross train MSLI analytical chemistry staff in Level 2 CT methods.
- Work with the Massachusetts Department of Environmental Protection and the US EPA Region 1 Laboratory to provide CT testing in environmental media.
- Work with the Massachusetts Department of Food & Agriculture, Pesticide Analysis Laboratory and the US FDA to provide CT testing in food products.

*Timeline: What are the critical milestones and completion dates for each task?*

- Join the chemical component of the LRN as a Level Two Laboratory *Expected completion date October 2003 (RT)*
- Develop detailed protocols for collection, shipping and handling of biological specimens



from exposed or potentially exposed individuals. *Complete September 2000*

- Attend training at CDC for analytical methods for trace metals, cyanide and lewisites. *Expected completion date July 2004 (CT Staff)*
- Implement LRN validated methods for these chemical agents in biological samples at the MSLI. *Expected completion date September 2004 (JN, CT Staff)*
- Participate in LRN/CDC sponsored proficiency testing. *Expected completion date September 2004 (JN, CT Staff)*
- Cross train MSLI analytical chemistry staff in Level 2 CT methods. *On going activity (CT Staff, Analytical Chemistry Staff)*
- Work with the Massachusetts Department of Environmental Protection and the US EPA Region 1 Laboratory to provide CT testing in environmental media. *Expected completion date March 2004. (JN, RT, MG, CT Coordinator)*
- Work with the Massachusetts Department of Food & Agriculture, Pesticide Analysis Laboratory and the US FDA to provide CT testing in food products. *Expected completion date March 2004. (JN, RT, MG, CT Coordinator)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Successful progress will be determined by MSLI joining the chemical component of the LRN as a Level 2 laboratory and is able to implement protocols for measuring heavy metals, cyanide and lewisites in biological specimens from exposed or potentially exposed individuals.

5. Enhance relationships with other chemical terrorism-related resources such as poison control centers, emergency medical personnel, medical toxicologists, food regulatory laboratories, schools of public health, and other partners with a view to ensuring that medical and public health officials have the benefit of at least preliminary chemical laboratory analyses in time to facilitate both the care of victims and the management of the incident. To this end, sponsor outreach efforts, professional conferences, and meetings.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

Massachusetts is fortunate in that the Boston Metropolitan Area is has concentrated resources that can contribute to the understanding, treatment and response to a chemical terrorism incident. Boston is a center of higher education with many colleges and universities located here including three medical schools and schools of public health (Harvard, Boston University and Tufts University). The University of Massachusetts Medical School and School of Public Health is headquartered in nearby Worcester, Massachusetts. The MSLI is located on the Jamaica Plain campus of UMMS. Tufts University also has a school of veterinary medicine within an hour of Boston. These academic institutions coupled with an integrated poison control system and

numerous well respected, teaching hospitals in Massachusetts provide the opportunity for enhanced relationships and collaborations to determine which if any laboratory tests are appropriate to facilitate patient care and incident management.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Establish chemical terrorism advisory workgroup of the *Bioterrorism Emergency Preparedness and Response Program Advisory Committee*. The membership of the workgroup will include representation from poison control centers, the medical community, academia and food and environmental testing laboratories.
- MSLI will conduct and or sponsor professional conferences and meetings to inform the medical and public health communities in incident management and victim care and facilitate discussion regarding appropriate laboratory testing.

*Timeline: What are the critical milestones and completion dates for each task?*

- Establish chemical terrorism advisory workgroup of the *Bioterrorism Emergency Preparedness and Response Program Advisory Committee*. The membership of the workgroup will include representation from poison control centers, the medical community, academia and food and environmental testing laboratories. *On-going activity (JN, CT Coordinator, RT, MG)*
- MSLI will conduct and or sponsor professional conferences and meetings to inform the medical and public health communities in incident management and victim care and facilitate discussion regarding appropriate laboratory testing. *Expected completion date September 2004 (CT Coordinator, CT Staff, Medical community, State Training Advisor)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Success will be measured by the active participation of the various stakeholders in training, professional conferences and the development of guidelines regarding laboratory testing for patient care and incident management.

**ENHANCED CAPACITY #7 (Level-Two laboratories):** In addition to establishing Level-One capacity, Level-Two Laboratories are to establish adequate and secure laboratory facilities, reagents, and equipment (e.g., ICP-MS, GC-MSD) to rapidly detect and measure in clinical specimens Level-Two chemical agents (such as cyanide-based compounds, heavy metals, and lewisites). Currently, CDC methods for Level-Two chemical agents use analytical techniques of inductively coupled plasma mass spectrometry and gas chromatography mass spectrometry. The

list of Level-Two chemical agents may expand as better methods are developed. Tandem mass spectrometry methods are not required for Level-Two chemical agents. *Prerequisite: To be eligible for Level-Two funding, the recipient must document a basic level competency in analytical chemistry and laboratory quality control in measurements of low concentrations of chemicals in clinical samples. Evidence of such competency would include a laboratory program in existence for at least one year that includes the quantitative measurement of low levels of a chemical in blood, urine, or environmental specimens (e.g., blood lead analysis program, EPA certification for chemical contaminant analyses of drinking water, or CLIA certification for clinical chemistry measurements).*

#### RECIPIENT ACTIVITIES:

1. Develop or enhance plans and protocols that address: (a) clinical specimen transport and handling, (b) worker safety, (c) appropriate Bio-Safety Level (BSL) conditions for working with clinical specimens, (d) staffing and training of personnel, (e) quality control and assurance, (f) internal and external proficiency testing, (g) triage procedures for prioritizing intake and testing of specimens or samples before analysis, (h) secure storage of critical agents and samples of forensic value, and (i) appropriate levels of supplies and equipment needed to respond to chemical terrorism events. This should be documented in your comprehensive response plans.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

The Environmental Chemistry Laboratory at the SLI has extensive experience in the analysis of complex sample matrices for chemical contaminants and naturally occurring toxins of public health concern and is therefore well qualified to become a Level Two laboratory in the chemical terrorism component of the LRN. This laboratory is a 4800 ft<sup>2</sup> analytical facility with designated wet chemical and instrumentation laboratories. The wet laboratories are equipped with ample chemical fume hood and bench space to safely and efficiently process, extract, distill and derivatize specimens for instrumental analysis. The instrumentation laboratories are equipped with sophisticated analytical instruments for the identification and quantitation of organic and inorganic chemical agents including GC/MSD, GC/ECD, HPLC/FL, HPLC/UV, FTIR, GFAAS, AAS, and XRF. The laboratory is accustomed to providing high quality testing in situations that require rapid response. For example, the Environmental Chemistry Laboratory quickly analyzed urine specimens from 190 residents of a Massachusetts town for total arsenic in response to community concerns of exposure. The laboratory also has the capacity and infrastructure for high throughput testing, analyzing more than 130,000 pediatric blood lead specimens last year with 24-hour turnaround.

MSLI will request as part of this proposal to augment our existing instrumentation with an ICP/DRC/MS and a GC/MSD with headspace sampling to expand our capability to measure inorganic and organic toxicants (trace metals, cyanide and lewisites) in biological matrices.. The Environmental Chemistry Laboratory is experienced at using biomarkers as a measure of exposure to chemical agents. To date, the MDPH has used targeted biomonitoring to assess exposure in individuals living near known sources of chemical contamination, in areas with increased prevalence of disease of possible environmental origin and in response to community fears of potential exposure. Examples of human exposure assessments conducted in collaboration

with MDPH Bureau of Environmental Health Assessment include:

- Measurement of specific PCB congeners and selected organochlorine pesticides in serum of women diagnosed with breast cancer and in a control group with no known breast disease;
- Evaluation of the efficacy of home de-leading in reducing exposure to lead paint by determining pediatric blood lead concentrations pre- and post abatement; and
- Analysis of hair and urine from children living in proximity to a hazardous waste incinerator for total arsenic.

In addition to testing human biological tissues for chemical contaminants, the Environmental Chemistry Laboratory has the capability to analyze other complex sample matrices for chemical agents. These include: PCBs in fish and milk:

- Organophosphate (OP) and methyl carbamate pesticides in fish, water and produce;
- Organochlorine pesticides (OC) in fish and produce;
- Ethylene dibromide in grains, produce, fish and cranberries;
- Mercury and methylmercury in fish;
- Lead in paint, soil, drinking water and household dust;
- Saxitoxin and related alkaloid toxins (paralytic shellfish poisoning) in seafood;
- Domoic acid (amnesic shellfish poisoning) in seafood;
- Histamine and related biogenic amines (scombroid poisoning) in seafood and
- Cyanide in a variety of food and pharmaceutical products.

These varied and sophisticated analyses require that the staff have the flexibility and creativity to quickly implement and optimize new methodology and to validate assays.

Trace chemical analyses in complex sample matrices are very challenging. A comprehensive quality assurance program, such as the one at MSLI is required to assure the accuracy of the laboratory data. The commitment to quality practices is evident at all staffing levels, from the MSLI laboratory director to analytical chemists to support staff. MSLI has a proactive quality assurance department that provides educational opportunities to staff and oversight of laboratory testing. Senior managers meet monthly to discuss policy, review any corrective actions and identify areas for improvement. Analysts in the Environmental Chemistry Laboratories are acutely aware of the importance of quality control and quality assurance to successful completion of their analyses. They must assess the quality of the sampling and laboratory supplies and reagents prior to use to ensure the products are free of contaminants or interferences that could compromise the testing. Typically, multiple levels of bench control are analyzed concurrently with unknowns to evaluate sample processing and analytical instrumentation performance. Control data are displayed graphically and reviewed by the analyst and a supervisor for conformance with predetermined standards. Data are monitored for trends

and bias and appropriate corrective actions are taken as needed.

In addition, the Environmental Chemistry Laboratory successfully participates in a number of proficiency testing programs to assess analytical competency. They are listed below:

- *New York Department of Health – blood lead and zinc protoporphyrin*
- *College of American Pathologists – blood lead*
- *Quebec Centre du Toxocolgie – urinary arsenic (total) and mercury*
- *Institut nationale de sante publique du Quebec - serum PCB congeners and organochlorine pesticides (AMAP Ring Test)*
- *NIOSH Environmental Lead Proficiency Analytical Program – paint, soil and household dust for lead*
- *SPEX – drinking water for lead and arsenic*
- *Department of Fisheries and Oceans Canada- biogenic amines in seafood*

The Environmental Chemistry Laboratory is “Accredited with Distinction” by the College of American Pathologists and has CLIA certification for the analysis of lead in blood. The laboratory has also been approved by the Occupational Health and Safety Administration to conduct occupational lead exposure evaluation. The laboratory is also certified by the Massachusetts Department of Environmental Protection, under the EPA Drinking Water Program, for the analysis of lead in drinking water. The laboratory will seek CLIA certification, if available for the remaining analytes involved in Level Two testing.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Hire three analytical chemists (1 laboratory supervisor II, 2 chemist III) to set up and validate methods for trace metals, cyanide and lewisites in biological specimens.
- Purchase the following equipment via Direct Assistance from CDC:
  - Perkin Elmer ELAN DRC ICP-MS for trace metals analysis;
  - Agilent 6890 gas chromatograph equipped with an Agilent 5973 Mass Selective Detector
  - Gerstel MPS Prepstation and autosampler
- Purchase additional equipment and supplies
  - Biological safety cabinet/chemical fume hood
  - Solid Phase Extraction /Solid Phase Micro Extraction System
  - Laboratory supplies
- Proficiency testing - participate in LRN/CDC sponsored proficiency testing for Level 2

CT agents in biological specimens.

- Train CT analytical staff on specific level 2 CT protocols at CDC.
- Attend vendor sponsored instrumentation training.
- Protocols
  - Develop detailed protocols clinical specimen collection, handling & transport in accordance with CDC/LRN guidelines and IATA and DOT regulations. *complete*
  - Update Chemical Hygiene Plan, Exposure Control Plan and MSLI Safety Manual to reflect the appropriate requirements for the safe use of use of Level Two CT agents and working with clinical specimens.
  - Triage procedures for prioritizing intake and testing of specimens or samples prior to analysis
- Renovate existing laboratory space to accommodate staff, instrumentation and an external facility to triage specimens upon receipt in the laboratory.
- Participate in CDC/LRN sponsored proficiency testing
- Seek CLIA certification for remaining analytes, as appropriate.
- Travel to CDC (2) to attend 50 state Focus Area C/D meeting

*Timeline: What are the critical milestones and completion dates for each task?*

- Hire three analytical chemists (1 laboratory supervisor II, 2 chemist III) to set up and validate methods for trace metals, cyanide and lewisites in biological specimens *Expected completion date February 2004 (JN, Environmental Chemistry staff)*
- Purchase the following equipment via Direct Assistance from CDC:
  - Perkin Elmer ELAN DRC ICP-MS for trace metals analysis;
  - Agilent 6890 gas chromatograph equipped with an Agilent 5973 Mass Selective Detector
  - Gerstel MPS Prepstation and autosampler

*Expected completion date February 2004 (JN, CDC)*

- Purchase additional equipment and supplies
  - Biological safety cabinet/chemical fume hood
  - Solid Phase Extraction /Solid Phase Micro Extraction System
  - Laboratory supplies

*Expected completion date –ongoing activity (JN, CT staff)*

- Proficiency testing - participate in LRN/CDC sponsored proficiency testing for Level 2 CT agents in biological specimens. *Expected completion date September 2004 (CT Staff)*
- Train CT analytical staff on specific level 2 CT protocols at CDC. *Expected completion date July 2004 (CDC, CT staff)*
- Attend vendor sponsored instrumentation training. *Expected completion date May 2004 (CT staff)*
- Protocols

- Develop detailed protocols clinical specimen collection, handling & transport in accordance with CDC/LRN guidelines and IATA and DOT regulations. *Complete*
- Implement LRN/CDC Level 2 CT protocols *Expected completion date September 2004 (JN, Ct Staff)*
- Update Chemical Hygiene Plan, Exposure Control Plan and MSLI Safety Manual to reflect the appropriate requirements for the safe use of use of Level Two CT agents and working with clinical specimens. *Expected completion date March 2004 (CT Coordinator, Health & Safety)*
- Triage procedures for prioritizing intake and testing of specimens or samples prior to analysis *Expected completion date February 2004 (CT Coordinator, MG, JN)*
- Renovate existing laboratory space to accommodate staff, instrumentation and an external facility to triage specimens upon receipt in the laboratory. *Expected completion date September 2004 (RT, JN, CT staff)*
- Participate in CDC/LRN sponsored proficiency testing *Expected completion date September 2004 (CT staff)*
- Cross train existing analytical chemistry staff in Level 2 CT methods to provide additional laboratory capacity. *On going activity (CT staff)*
- Seek CLIA certification for remaining analytes, as appropriate. *Expected completion date January 2005 (JN, CT Staff)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

MSLI successfully participates in the LRN/CDC sponsored proficiency testing program for toxic metals, cyanide and lewisites in biological specimens and has sufficient testing capacity to respond to a CT incident.

2. Level-Two laboratories must, in collaboration with CDC, purchase equipment, hire and train staff, implement analytical methods, participate in proficiency testing programs, and demonstrate competency in the analysis of Level-Two chemical agents or their metabolites in human specimens. Level-Two laboratories must achieve CLIA certification within 18 months of funding.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

MSLI is committed to being a Level Two LRN Laboratory with the intention of applying for Level Three status in the future. Having extensive experience in human biomonitoring and trace residue analysis in environmental media and complex food matrices, will be an asset as the

laboratory prepares for implementing the Level 2 CT methods for inorganic and organic toxicants (trace metals, cyanide and lewisites) in biological matrices. To accomplish this additional testing capability, the laboratory will augment our existing instrumentation with a Perkin Elmer ELAN ICP/DRC/MS and an Agilent GC/MSD with Gerstel headspace sampling and hire additional analytical staff. The dedicated employees will be trained at CDC in the specific methodology and also by the instrument vendors. The laboratory will demonstrate proficiency by participating in LRN/CDC sponsored PT rounds and will seek available CLIA certification beyond our current list of analytes.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Hire three analytical chemists (1 laboratory supervisor II, 2 chemist III) to set up and validate methods for trace metals, cyanide and lewisites in biological specimens
- Purchase the following equipment via Direct Assistance from CDC:
  - Perkin Elmer ELAN DRC ICP-MS for trace metals analysis;
  - Agilent 6890 gas chromatograph equipped with an Agilent 5973 Mass Selective Detector
  - Gerstel MPS Prepstation and autosampler
- Purchase additional equipment and supplies
  - Biological safety cabinet/chemical fume hood
  - Solid Phase Extraction /Solid Phase Micro Extraction System
  - Laboratory supplies
- Proficiency testing - participate in LRN/CDC sponsored proficiency testing for Level 2 CT agents in biological specimens.
- Train CT analytical staff on specific level 2 CT protocols at CDC.
- Attend vendor sponsored instrumentation training.
- Protocols
  - Develop detailed protocols clinical specimen collection, handling & transport in accordance with CDC/LRN guidelines and IATA and DOT regulations. *Complete*
  - Implement LRN/CDC Level 2 CT protocols
  - Update Chemical Hygiene Plan, Exposure Control Plan and MSLI Safety Manual to reflect the appropriate requirements for the safe use of use of Level Two CT agents and working with clinical specimens.
  - Triage procedures for prioritizing intake and testing of specimens or samples prior to analysis
- Renovate existing laboratory space to accommodate staff, instrumentation and an external facility to triage specimens upon receipt in the laboratory.
- Participate in CDC/LRN sponsored proficiency testing
- Cross train existing analytical chemistry staff in Level 2 CT methods to provide additional laboratory capacity.



- Seek CLIA certification for remaining analytes, as appropriate.

*Timeline: What are the critical milestones and completion dates for each task?*

- Hire three analytical chemists (1 laboratory supervisor II, 2 chemist III) to set up and validate methods for trace metals, cyanide and lewisites in biological specimens *Expected completion date February 2004 (JN, Environmental Chemistry staff)*
- Purchase the following equipment via Direct Assistance from CDC:
  - Perkin Elmer ELAN DRC ICP-MS for trace metals analysis;
  - Agilent 6890 gas chromatograph equipped with an Agilent 5973 Mass Selective Detector
  - Gerstel MPS Prepstation and autosampler

*Expected completion date February 2004 (JN, CDC)*

- Purchase additional equipment and supplies
  - Biological safety cabinet/chemical fume hood
  - Solid Phase Extraction /Solid Phase Micro Extraction System
  - Laboratory supplies

*Expected completion date –ongoing activity (JN, CT staff)*

- Proficiency testing - participate in LRN/CDC sponsored proficiency testing for Level 2 CT agents in biological specimens. *Expected completion date September 2004 (CT Staff)*
- Train CT analytical staff on specific level 2 CT protocols at CDC. *Expected completion date July 2004 (CDC, CT staff)*
- Attend vendor sponsored instrumentation training. *Expected completion date May 2004 (CT staff)*
- Protocols
  - Develop detailed protocols clinical specimen collection, handling & transport in accordance with CDC/LRN guidelines and IATA and DOT regulations. *Complete*
  - Implement LRN/CDC Level 2 CT protocols *Expected completion date September 2004 (JN, Ct Staff)*
  - Update Chemical Hygiene Plan, Exposure Control Plan and MSLI Safety Manual to reflect the appropriate requirements for the safe use of use of Level Two CT agents and working with clinical specimens. *Expected completion date March 2004 (CT Coordinator, Health & Safety)*
  - Triage procedures for prioritizing intake and testing of specimens or samples prior to analysis *Expected completion date February 2004 (CT Coordinator, MG, JN)*
- Renovate existing laboratory space to accommodate staff, instrumentation and an external facility to triage specimens upon receipt in the laboratory. *Expected completion date September 2004 (RT, JN, CT staff)*

- Participate in CDC/LRN sponsored proficiency testing *Expected completion date September 2004 (CT staff)*
- Cross train existing analytical chemistry staff in Level 2 CT methods to provide additional laboratory capacity. *On going activity (CT staff)*
- Seek CLIA certification for remaining analytes, as appropriate. *Expected completion date January 2005 (JN, CT Staff)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Activity will be determined to be successful if the laboratory implements the Level 2 methods and successfully participates in LRN/CDC proficiency testing for trace metals, lewisites and cyanide.

### 3. **CRITICAL BENCHMARK #16 – APPLICABLE TO LEVEL-TWO**

**LABORATORIES ONLY:** Participate in at least one exercise per year that specifically tests chemical terrorism laboratory readiness and capability to detect and identify at least one chemical-threat agent.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

In conjunction with local first responders, federal partners and area hospitals the laboratory will participate in simulation exercise that tests chemical terrorism readiness at least annually. Ideally, this exercise will include as many facets of response as possible.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

The simulation exercise will evaluate each of the following components of the response effort:

- Emergency response
- Field screening
- Sample collection
- Laboratory analyses
- Patient management
- Data reporting
- Risk management and risk communication

*Timeline: What are the critical milestones and completion dates for each task?*

Successful participation in an exercise that tests and challenges the system. *Expected completion September 2004 (All)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

RT  
MG  
CT Staff  
JN  
First responders  
Hospitals  
Clinical and commercial laboratories

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

An evaluation report written by an unbiased observer will critique the various aspects of the response and make recommendations for improvement.

4. Use BSL-2 practices, as outlined in the CDC-NIH publication “Bio-safety in Microbiological and Biomedical Laboratories, 4<sup>th</sup> Edition” (BMBL), to process clinical specimens (e.g., blood and urine) – see [www.cdc.gov/od/ohs](http://www.cdc.gov/od/ohs). [CDC also recognizes the need that state laboratories have to safely handle unknown environmental samples. Laboratories are encouraged to participate with federal partners, the LRN, HAZMAT, first responders, and other state public health laboratories to develop and disseminate standardized methods, procedures, and protocols to safely triage, aliquot, transfer, ship, and store unknown clinical or environmental specimens potentially containing chemical, biological, radiological, or explosive agents. \(LINK WITH FOCUS AREA C\)](#)

*Strategies: What overarching approach(es) will be used to undertake this activity?*

Employee health and safety are of great concern when processing unknown samples involved in a chemical terrorism incident. The potential exists for multiple hazards to present in a single specimen. MSLI proposes to take an all hazards approach when receiving specimens to the laboratory. While the screening protocols will be developed in partnership with the federal, state and local law enforcement agencies, MSLI has purchased some instrumentation to evaluate unknowns prior to bringing them into the main laboratory facility. This external screening is hoped to protect workers from the risks associated with explosives, nerve and blister agents and radiation. as well as preventing gross contamination of the laboratory facility. MSLI purchased two portable ion mobility detectors *Smith Detection Systems Saber 2000*, *Ludlum Model 44-89 GM pancake cluster detector for radiation and a Ludlum Model 375 Area Radiation Monitors*.

We propose to renovate space external to the main laboratory facility to provide a safe and secure facility for the triage and gross screening of unknown samples. We will begin by evaluating designs created by Battelle associates for the US Centers for Disease Control to determine the feasibility of developing a similar space at MSLI.

We also propose to renovate space in the Environmental Chemistry Laboratories to accommodate additional staff, analytical instrumentation and wet chemistry workspace. All renovated areas, including the triage room will meet Biosafety Level 2 standards as defined in “Bio-safety in Microbiological and Biomedical Laboratories, 4<sup>th</sup> Edition” (BMBL).

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Ensure worker safety by implementing Biosafety Level 2 practices. *Complete*
- Purchase equipment to screen unknown samples for chemical warfare agents, radiation and explosives. *Complete*
- Evaluate architectural plans for an external facility to triage and screen unknown samples developed by Battelle for CDC.
- Renovate external laboratory space to create a safe & secure location for sample screening and triage.
- Renovate laboratory space to create additional sample preparation workspace and accommodate new instrumentation.
- Work with federal partners, law enforcement, LRN, HAZMAT to develop standardized practices for sample triage and screening assuming an all hazards approach

*Timeline: What are the critical milestones and completion dates for each task?*

- Evaluate architectural plans for an external facility to triage and screen unknown samples developed by Battelle for CDC. *Expected completion date December 2003 (RT, JN, MG)*
- Renovate external laboratory space to create a safe & secure location for sample screening and triage. *Expected completion date September 2004. (RT, JN, MG, Facilities)*
- Renovate laboratory space to create additional sample preparation workspace and accommodate new instrumentation. *Expected completion date September 2004 (JN, CT Lab Supervisor, Facilities, RT)*
- Work with federal partners, law enforcement, LRN, HAZMAT to develop standardized practices for sample triage and screening assuming an all hazards approach *Expected completion date March 2004 (CT Coordinator, JN, MG)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Detailed triage protocols are developed and safe and secure facilities are available for specimen receipt, triage, processing and analysis.

5. At a minimum, ensure that laboratory security is consistent with standards set forth in the Select Agent Rule or subsequent updates. Note that pursuant to 18 USC section 175b, as amended by section 817 of the USA PATRIOT Act of 2001, P.L. 107-56, aliens (other than aliens lawfully admitted to the United States for permanent residence) are prohibited from possessing select agents if they are nationals of countries about which the Secretary of State (pursuant to provisions of the Export Administration Act of 1979, the Foreign Assistance Act of 1981, or the Arms Export Control Act) has made an unrevoked determination that such countries have repeatedly provided support for acts of international terrorism.

*Strategies: What overarching approach(es) will be used to undertake this activity?*

Access to the State Laboratory Institute (SLI) is controlled by electronically recorded card swipe readers at all entrances. All visitors are required to sign in at the front reception desk and are escorted by laboratory staff. Frequent visitors can be issued a color-coded temporary visitor pass, which allows unescorted access to unrestricted areas within the building designated by the color code. Presently, security cameras are positioned to record activity at the loading dock and rear service entrance of the building as well as the parking lot, however these records are not archived. By September 2003, security cameras will be installed to digitally record all entrances of the building as well as hallways and doorways of restricted areas. These digital files will be saved and stored in a secure location. The State Laboratory Institute is currently undergoing a vulnerability assessment conducted by the Massachusetts State Police. In addition to the placement of security cameras, this assessment will indicate other security measures that need to be instituted to secure the SLI.

A laboratory security system has been installed to monitor and control access to restricted laboratories and storage areas within SLI as outlined in MMWR December 6, 2002. This system allows for unescorted access to only those individuals approved by the laboratory director and who are performing a specifically authorized function. Provisions are also included for routine cleaning, maintenance and visitor access by escort. The system ensures that all individuals with access are properly trained to follow procedures.

Individual laboratory doors are secured by electric magnetic locks and entry is controlled by dual authentication proximity card reader and fingerprint scanner (both mechanisms are required to release the magnetic locks). Exiting the laboratory is controlled by proximity card reader or emergency release buttons. Any forced entry will send alarms via wireline and wireless telephones, pagers and email. All entries and exits of restricted laboratories are electronically recorded and periodic reports are generated summarizing which approved individuals were in a restricted laboratory at any given time. A detailed audit trail is also electronically maintained to record all server activity, including additions, modifications and deletions to the system.

Within individual restricted laboratories, freezers, refrigerators, cabinets and other containers where select agents and toxins are stored remain locked at all times with limited access by key or combination. Procedures are in place for replacing compromised keys and combinations. Daily use of select agents and toxins is recorded and monthly inventories of all containers of select agents and toxins are conducted with provisions for reporting loss, theft and accidental release of agents.

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Additional proximity card/fingerprint readers will be installed on laboratory and walk in freezer doors
- Background checks will be conducted, as required on chemical terrorism staff)
- Surveillance cameras will be installed
- Access to hallways on laboratory floors will be restricted

*Timeline: What are the critical milestones and completion dates for each task?*

- Additional proximity card/fingerprint readers will be installed on laboratory and walk in freezer doors. . *Expected completion date November 2004 (JN, MG)*
- Background checks will be conducted, as required on chemical terrorism staff  
*Expected completion date May 2004 (Massachusetts State Police, US Department of Justice)*
- Installation of surveillance cameras *Expected completion date September 2004 (MG, CT Coordinator)*
- Restricted hallway access *Expected completion date September 2004 (MG, CT Coordinator)*

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

See above

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

Worker and facility safety are assured by having sufficient procedures, engineering controls, protective equipment and screening devices to protect against multiple, simultaneous hazards.

6. Enhance and document Internet connectivity to enable rapid communication via the Internet for information and data transfer with chemical laboratories in the LRN. **(LINK WITH FOCUS AREA C & E)**

*Strategies: What overarching approach(es) will be used to undertake this activity?*

The MSLI will continue to enhance its electronic communications capabilities to provide secure, timely test reporting and surveillance information to the LRN, other private entities and government agencies to support public health disease reporting and surveillance activities. MSLI has recently completed the conceptual design of the MSLI Electronic Laboratory Reporting and Communication (ELR) Component. The ELR component will allow MSLI to provide secure client transactions through web-based communications.

The ELR component is an extranet application that will extend the functionality of the recently developed State Laboratory Information System (SLIS). SLIS includes a common data repository (CDR) that will be accessed by all laboratories within the MSLI. The CDR is based on the

NEDSS/HL7 logical data model and utilizes common database technology (SQL Server) using Windows NT and supports ODBC connectivity.

The conceptual design of the ELR Component includes the use of a commercial interface engine as a solution for both ELR and SLIS transmission and reception of HL7 messages and data. The interface engine will be selected to support HL7, Version 2.4 and earlier, ebXML, message queues and the ability to translate and manipulate LOINC and SNOMED codes. The web interface will use standard web security features of the web server platform, which will be selected during the detailed design phase, and include strong authentication connectivity. These include HTTP User Authentication and session encryption using HTTPS and secure socket layer (SSL).

*Tasks: What key tasks will be conducted in carrying out each identified strategy?*

- Define the detailed requirements of the ELR Component of State Laboratory Information Systems (SLIS) to report laboratory results to the LRN, other private entities and government agencies using HL7 messaging and remote laboratory test result inquiry capabilities.
- Determine the readiness of select hospitals and laboratories to report results electronically including an evaluation of their HL7 interface capabilities.
- Ensure that system participants have Internet Connectivity and that the connection is a minimum of 56Kbps or ideally 384 Kbps or greater and can support 128 bit encryption
- Create functional specifications that include the defined business logic, data requirements and information processing. This also will include the identification of potential COTS solutions
- Refine technical architecture including specifications of the optimum technology associated with the hardware, software, communications and interface of the ELR Component. The architecture will include integration with the SLIS application within an n-tier architecture.

*Timeline: What are the critical milestones and completion dates for each task?*

07/03 – 09/03: Define the detailed requirements of the ELR Component

07/03 – 09/03: Determine the readiness of select hospitals and laboratories to report results electronically

07/03 – 09/03: Ensure that system participants have Internet Connectivity

09/03 – 12/03: Create functional specifications

12/03 – 03/04: Refine technical architecture

*Responsible Parties: Identify the person(s) and/or entity assigned to complete each task.*

Dina Caloggero (QA and Informatics Manager), Henry Cheung (EDP Systems Analyst), John Schaeffer/Jim Daniel (CD Bureau) and the TBD (EDP Systems Analyst) will complete the above tasks.

*Evaluation Metric: How will the agency determine progress toward successful completion of the overall recipient activity?*

The ELR Component will be developed in accordance with the Massachusetts Department of Public Health, Systems Development Life Cycle (SDLC) methodology. Metrics will be employed on selected tasks as appropriate to monitor performance, identify potential issues as early as

possible in the SDLC process and determine the effectiveness of remedial actions taken. Major milestones dates will be monitored as to the estimated and actual completion dates. Once the metrics are defined and gathered, they will be communicated regularly to the MSLI Project Team for project tracking and process improvements.